PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 :
A61B 8/12

A1

(11) International Publication Number: WO 00/40156

(43) International Publication Date: 13 July 2000 (13.07.00)

(21) International Application Number: PCT/GB99/04343

(22) International Filing Date: 22 December 1999 (22.12.99)

(30) Priority Data:
9900133.1 6 January 1999 (06.01.99) GB

(71) Applicant (*for all designated States except US*): INTRAVASCULAR RESEARCH LIMITED [GB/GB]; Unit 3a Centaurs Business Park, Grants Way, Isleworth, Middlesex TW7 5QD (GB).

(72) Inventors; and
(75) Inventors/Applicants (*for US only*): GLOVER, Richard, Peter [GB/GB]; 23 Kerrison Road, Ealing, London W5 5NW (GB). STENNING, Anthony, David [GB/GB]; 13 Henchley Dene, Herrow Common, Guilford, Surrey GU4 7BH (GB). DICKINSON, Robert, Julian [GB/GB]; 37 Broomwood Road, Battersea, London SW11 6HU (GB).

(74) Agent: ATKINSON BURRINGTON; The Technology Park, Skirland Lane, Sheffield S9 3PA (GB).

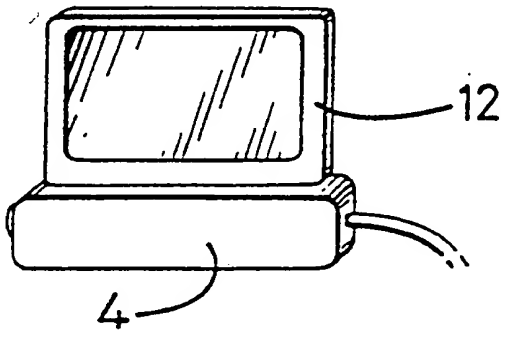
(81) Designated States: JP, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: ULTRASONIC VISUALISATION SYSTEMS

(57) Abstract

In an IVUS system units are located outside or remote from the patient except for the display monitor (12), the catheter interface module (4) and the catheter (3) which are located adjacent the patient together with a control arrangement (13) to enable the said units to be remotely controlled from a position adjacent the patient.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

Ultrasonic Visualisation Systems

Introduction to the Invention

The present invention relates to ultrasonic visualisation systems and more particularly to systems of the kind to which our United Kingdom patent 2,233,094 and United States patent 5,257,629 relate. Such systems will hereinafter be referred to as intravascular ultrasound systems or IVUS.

Such systems include various units such as a cathode ray tube monitor, an ultrasound processing unit, a power distribution unit, and possibly a video recorder (VCR), together with a video printer as well as the catheter to be inserted into the patient and a catheter interface module linking the catheter to the other units referred to.

It has been proposed to mount the above types of unit in a cart or trolley that can be manoeuvred into an appropriate position within the catheter laboratory or other relevant environment.

In such an arrangement the catheter and its associated catheter-interface-module (CIM), are not mounted on the cart or trolley because the catheter is to be inserted into the patient and the CIM would typically rest on or near the patient.

The floor area adjacent to the patient is at a premium because of the need to accommodate the medical team close to the patient. As a result, it is usually necessary to locate the cart or trolley some distance from the patient which in turn means that the display monitor has to have a reasonably large screen in order for the displayed image to be clearly visible to the clinician.

Summary of The Invention

The present invention is concerned with the physical location of such units of the system in order to improve the operating environment for the medical team.

According to one aspect of the present invention in an IVUS system the said units are located outside or remote from the patient except for the display monitor, the CIM and the catheter which are located adjacent the patient together with a control arrangement to enable the said units to be remotely controlled from a position adjacent the patient.

According to a first aspect of the present invention, the display monitor comprises a flat screen monitor such as a liquid crystal display.

Because the monitor can now be located much nearer to the patient it can be made much smaller and still provide the clinician with a clearly visible image.

According to a second aspect of the present invention, the control arrangement incorporates means to enable control instructions to be given by voice and incorporates voice recognition means for accepting and implementing those instructions.

According to a third aspect of the present invention, an IVUS system is embedded in a conventional ultrasound system which employs a transducer placed externally of the patient so that units of the conventional ultrasound system can also be employed in the IVUS system thus avoiding the duplication of those units. In other words, certain units are common to both the conventional ultrasound system and the IVUS system.

According to a fourth aspect of the present invention, the IVUS system is embedded in an existing X-ray system, again so that units common to both systems can be shared.

According to a fifth aspect of the present invention, the control

arrangement includes an infrared remote control device to enable control instructions to be given from a position adjacent the patient to the remotely located units.

According to a sixth aspect of the present invention, the monitor is mounted on the CIM unit.

Brief Description of The Drawings

Figure 1 is a perspective view of a known mobile cart or trolley of the kind already described;

Figure 2 is a perspective view of a combined display and catheter-interface-module according to the present invention;

Figure 3 is a diagrammatic representation of an IVUS embedded in a standard X-ray room according to the present invention;

Figure 4 is a block diagram showing an IVUS embedded in a personal computer according to the present invention; and

Figure 5 is a block diagram showing a single board IVUS embedded in an ultrasound system.

Detailed Description of The Preferred Embodiments

A cart or trolley **1** is provided with casters **2** by which it can be manoeuvred within a catheter laboratory or other relevant environment.

A catheter **3** for insertion into a patient, is connected to a catheter interface module **4** which in turn is connected by a cable **5** to the various units carried by the trolley **1**.

These units typically comprise a cathode ray tube monitor **6** mounted on the top of the cart or trolley **1**, a keyboard and trackball **7** for controlling the display on the monitor, a power distribution unit **8**, an ultrasound

processing unit **9** (which could be a personal computer), a video recorder (VCR) **10** and an associated video printer **11**.

The cart or trolley **1** typically comprises a framework **1a** and a number of shelves **1b**.

As discussed earlier, the cart or trolley arrangement shown in *Figure 1* would be located within the catheter laboratory or other relevant environment as close as possible to the patient without taking up floor space which would be needed by the medical team adjacent the patient. As a result the size of the screen of the monitor **6** has to be relatively large in order to provide a clear and visible display to the clinician.

The essence of the present invention is the elimination of the trolley or cart **1** and the positioning at a remote location of most of the units normally carried by the trolley as shown in *Figure 1*.

The only units which would be located adjacent the patient are the CIM **4**, a display screen **12** mounted on the CIM **4**, and a control panel **13** by which the various units making up the system can be controlled. The catheter **3** is of course close to the patient as it has to be inserted into the patient.

Because the screen of the monitor **12** is close to the patient and therefore to the clinician, that screen can be much smaller than the screen of the known arrangement of *Figure 1*.

In fact, instead of comprising a cathode ray tube display, the monitor **12** could comprise a flat liquid crystal display or other type of flat screen display.

The control panel can be through a simple local control such as a trackball, joy stick or similar pointing device, combined with Windows based software, and be very small. Alternatively, the control can be mounted with

other control devices such as an X-ray gantry and bed controls.

To make control of the system easier a remote handset could be used. This could operate through an infrared link (or similar wireless communication), to the bedside unit, or directly with the processing hardware as an alternative where the room configuration demands it. This handset could provide all the controls required to run the IVUS system such as adjusting gain, image magnification etc, and replaces the slides and buttons of a normal IVUS system.

According to a further aspect of the present invention, the system control could make use of voice-recognition technology. Here the handset could be employed with links to the processing hardware. System generated speech could be employed to allow interaction between operator and system that would make the need for close observation of the display less important. Recognition of key words could allow any function to be activated etc. Text entry could be managed in a similar way.

The advantages of the arrangements according to the present invention, so far described, is that the processing hardware is now free of display and interface devices such as a keyboard, and can be made small enough to be positioned in a convenient place such as underneath the patient's bed.

Overhead monitors in the room can be used as an alternative or additional display.

Alternatively, it can be housed with the X-ray electronics in the X-ray control room, an arrangement of this kind being shown in *Figure 3*. The IVUS system can then make use of the standard peripherals such as printers and digital or video recorders already provided in the X-ray room. The processing hardware in the control room can also be provided with a

parallel set of operating controls to enable operation from outside the catheter lab, by a suitable operator, and a patient's details can be entered from this control room.

Referring to *Figure 3*, a patient's bed is indicated at **14** with the arrangement shown in *Figure 2* adjacent the bed.

The CIM **4** is connected to the IVUS computer **9** through an electrical connection **15** and a remote control joystick-type arrangement **16** is also connected to the computer **9** through an electrical connection **17**.

All the other units required to make the IVUS system operative are already incorporated in the known standard X-ray equipment.

The data processing performed in an IVUS system consists of a series of discrete operations arranged in what is known as a pipeline. This means that the output of one process is the input of the next process. These processes can be arranged as separate modules, such as individual circuit cards, that are linked through a standard interface. An example of this is a set of dedicated cards that plug in to a peripheral component interconnect (PCI), computer bus. It then becomes possible to utilise commonly available standard cards or components to perform some of the non-IVUS specific processing such as data storage and archive, display drivers and power supplies. In this example the processing could be performed in a standard personal computer.

Figure 4 illustrates an embodiment of the IVUS processing modules.

In *Figure 4* those items which are equivalent to items already described with reference to *Figures 1* to *3* have the same reference numerals.

In *Figure 4* the overall personal computer arrangement is illustrated within the box **18**.

Contained within the box **18** are the modules which are specific to the IVUS system and these are contained within the smaller box **19**.

The modules which are within the box **18** but not within the smaller box **19** are those which could be standard items in many known imaging systems such as external ultrasound imaging systems.

These common units include a personal computer bus **20**, a scan conversation module **21**, a graphics card **22** and a unit such as a CD-ROM for storing data and archiving media **23**. The modules which are specific to the IVUS system in box **19** comprise an analogue to digital converter module **24** which takes an analogue input **25** from the catheter-interface-module **4**.

The output from the ADC **24** is raw digital data **26**, which is input to a digital signal processing card **27** which is concerned with focusing and beam forming.

The card **27** is interconnected with a data store **28** which itself is also interconnected with the module **23**.

With this arrangement one module **24** performs all of the data-capture operations and also undertakes the interface with the catheter-interface-module **4**.

A second module **27** undertakes the intensive numerical calculations required to focus the received data signals. This is typically a focusing and noise reduction operation.

The output from **27** would typically be digital and have a much lower bandwidth than the input to this module. This output consists of focused A-scans which can be temporarily stored in a local disk **28**, and archived suitable removable media **23**. Alternatively, the output of module **21** can be stored and archived using a similar arrangement.

The module **21** performs scan conversion of the digital data to allow representation of it on raster-scanned display devices such as conventional computer monitors or video screens.

This operation is similar to the interpolation and zoom functions found in many imaging modalities.

The IVUS modality can therefore be incorporated into another imaging modality by utilising the following components:

(i) catheter-interface-module and display **4, 12**

(ii) control device **13**

(iii) data acquisition module **24**

(iv) digital processing module **27**

(v) it may be necessary to also incorporate a scan conversion card **21** into the box **19**.

In a further aspect of the present invention, and in particular of the processing hardware, the digital processing function could be incorporated into the IVUS data acquisition module.

This would employ custom digital chip design techniques resulting ASICs or FPGAs to embed the processing operation. An example of which is synthetic aperture processing.

The system could then consist of a single module that can be incorporated into another imaging modality such as conventional external ultrasound. The same technique could also be used in standard computer systems to provide IVUS.

Figure 5 illustrates an embodiment of such an arrangement. Where those units or components which correspond with ones already described and illustrated have the same reference numerals.

A conventional external ultrasound has a transducer **29** the output

signal of which inputs to a transmit/receive module **30** which in turn inputs to an analogue to digital converter (ADC) **31**, which in turn inputs to a digital beam former **32**. In parallel the IVUS system takes the signals from the transducers at the distal end of the catheter **3**, passes them through the catheter-interface-module **4** and the combined ADC and focusing/beam forming module **24-27**, the output of which is common with the output from the digital beam former **32**, both of which input into the scan converter **21** followed by the graphics memory **22** and the display **12**.

The dotted line **33** indicates the single board comprising essentially an IVUS system embedded in a known conventional ultrasound system.

Claims

1. In an IVUS system the units making up the system are located outside or remote from the patient except for the display monitor, the CIM and the catheter which are located adjacent the patient together with a control arrangement to enable the said units to be remotely controlled from a position adjacent the patient.

2. A system as claimed in claim **1** in which the display monitor comprises a flat screen monitor such as a liquid crystal display.

3. A system as claimed in claim **1** or **2** in which the control arrangement incorporates means to enable control instructions to be given by voice and incorporates voice recognition means for accepting and implementing those instructions.

4. An IVUS system embedded in a conventional ultrasound system which employs a transducer placed externally of the patient so that units of the conventional ultrasound system can also be employed in the IVUS system thus avoiding the duplication of those units. In other words, certain units are common to both the conventional ultrasound system and the IVUS system.

5. An IVUS system embedded in an existing X-ray system, again so that units common to both systems can be shared.

6. A system as claimed in any of claims **12** in which the control

arrangement includes an infrared remote control device to enable control instructions to be given from a position adjacent the patient to the remotely located units.

7. A system as claimed in any previous claim in which the monitor is mounted on the CIM unit.

8. A system substantially as hereinbefore described with reference to and as shown in *Figure 2*, or *Figure 3*, or *Figure 4*, or *Figure 5* of the accompanying drawings.

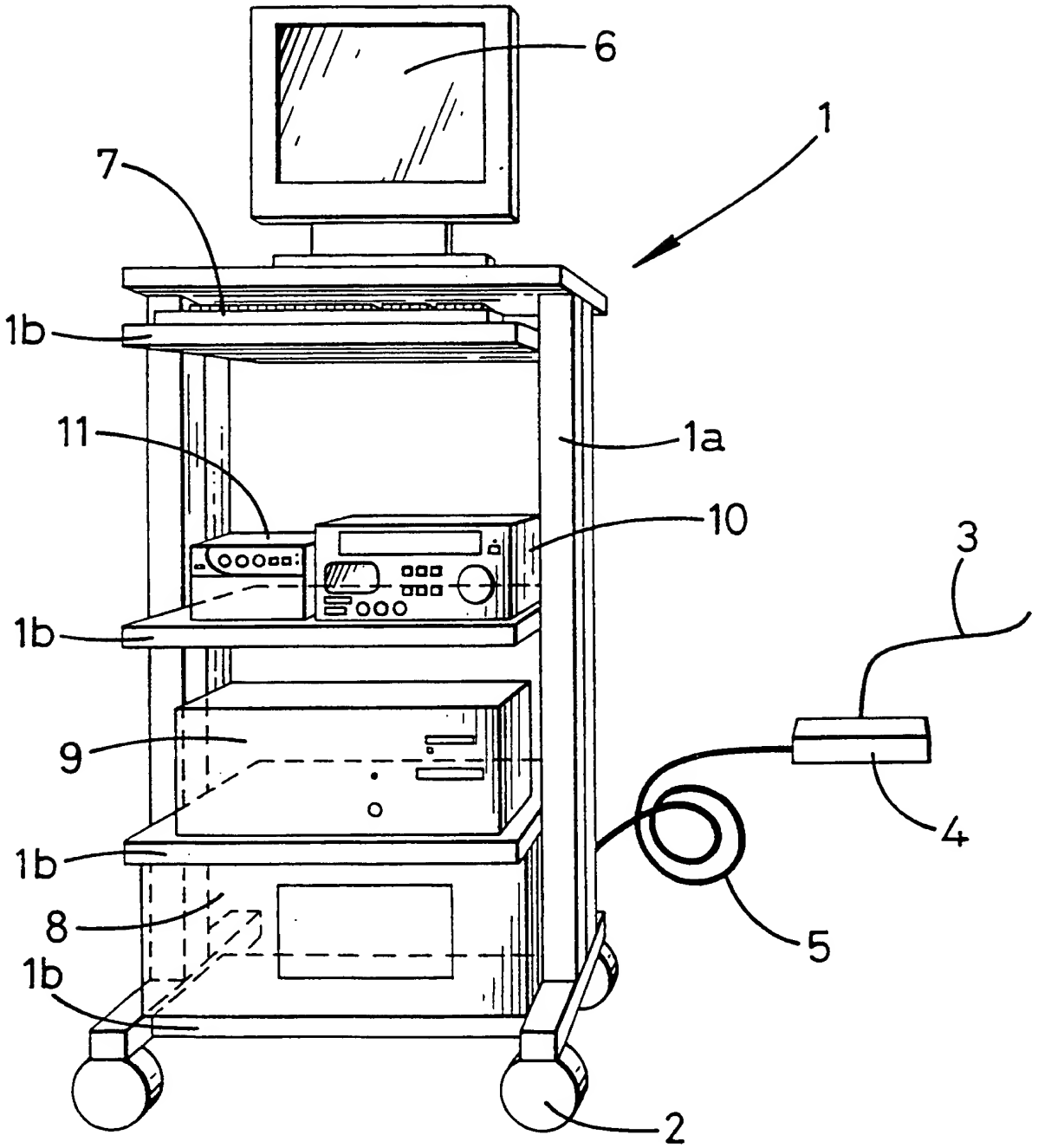


FIG. 1

FIG. 2

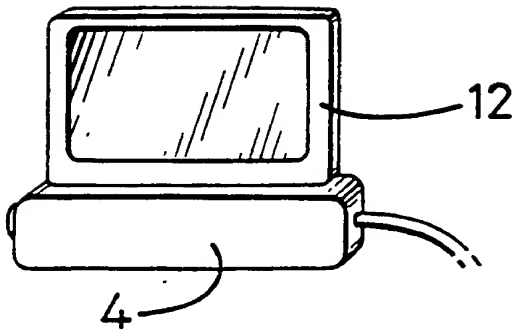


FIG. 3

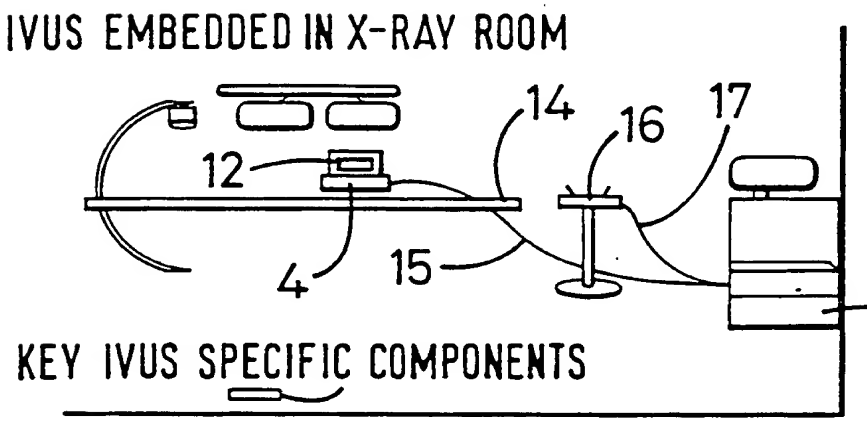
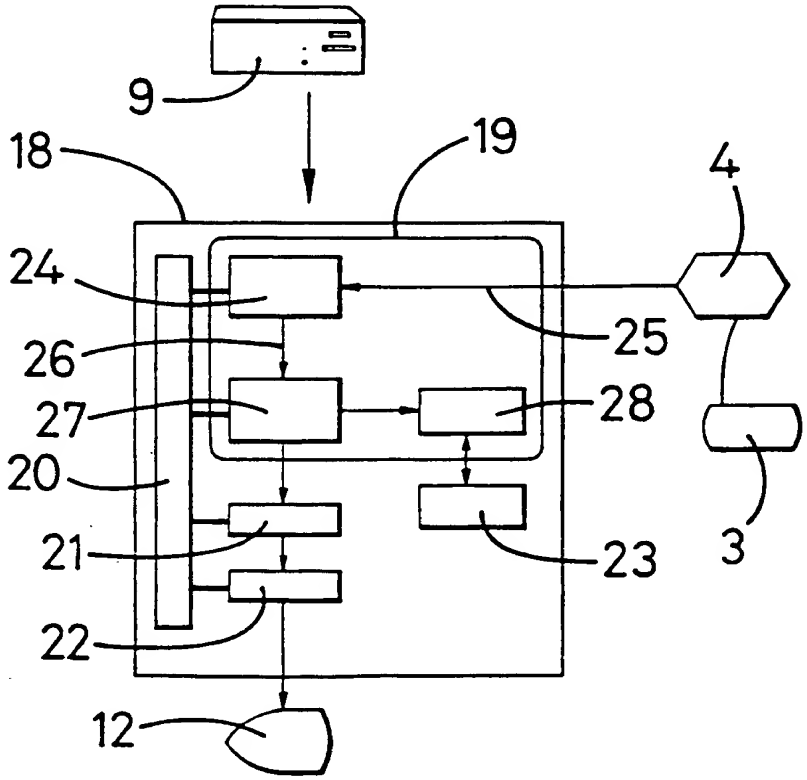


FIG. 4



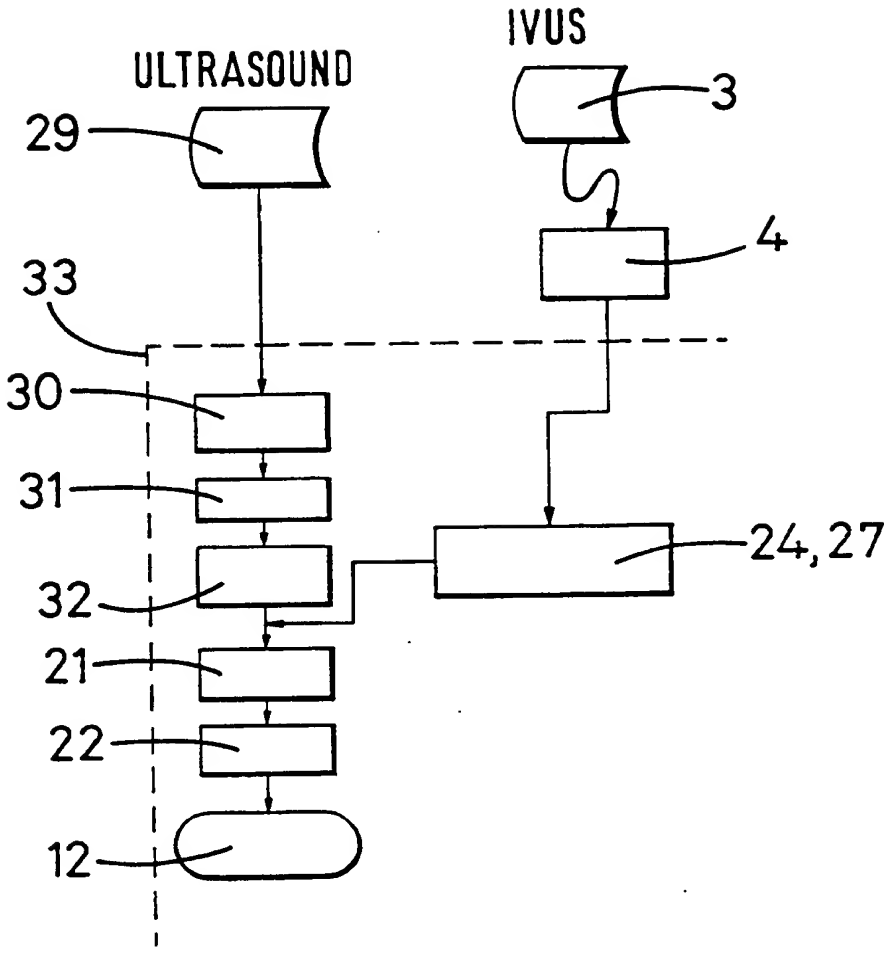


FIG. 5

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 99/04343

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B8/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B G01S

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 43 16 643 A (SIEMENS AG) 16 December 1993 (1993-12-16) column 1, line 47 - line 49 column 2, line 35 - line 67	1,3
A	US 4 625 731 A (QUEDENS PHILLIP J ET AL) 2 December 1986 (1986-12-02) column 4, line 14 - line 37	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 March 2000	14. 06. 2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Knüpling, M

1

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Inte tional application No.
PCT/GB 99/04343

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 8
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
See additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-3,6,7

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 8

The subject matter of claim 8 is defined by reference to the description and drawings which is not allowed by the PCT (see rule 6.2 PCT). The claim does not define any clear structural features or limitations. Consequently, the scope of the claim is not clear (see Article 6 PCT) and a meaningful search is not possible (Article 17 PCT).

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

1. Claims: 1-3,6,
7 (claim 7 if dependent on any of claims 1-3 or 6)

A remotely controllable intravascular ultrasound system

2. Claims: 4,5,
7 (claim 7 if dependent on any of claims 4 or 5)

Integration of an intravascular ultrasound system

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 99/04343

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE 4316643 A	16-12-1993	NONE	
US 4625731 A	02-12-1986	JP 61179139 A	11-08-1986

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Assistant Commissioner for Patents
United States Patent and Trademark Office
Box PCT
Washington, D.C.20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 28 August 2000 (28.08.00)	
International application No. PCT/GB99/04343	**Applicant's or agent's file reference**
International filing date (day/month/year) 22 December 1999 (22.12.99)	**Priority date** (day/month/year) 06 January 1999 (06.01.99)
Applicant GLOVER, Richard, Peter et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

04 August 2000 (04.08.00)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Zakaria EL KHODARY
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
IRL-P23-WO		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB99/04343	22/12/1999	06/01/1999
International Patent Classification (IPC) or national classification and IPC A61B8/12		
Applicant INTRAVASCULAR RESEARCH LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
04/08/2000	23.04.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Fontenay, P Telephone No. +49 89 2399 2646

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB99/04343

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-9	as originally filed			

Claims, No.:

1-10	as received on	22/12/2000	with letter of	20/12/2000

Drawings, sheets:

1/3-3/3	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   - ☐ the description, pages:
   - ☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)
   see separate sheet

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application.

   ☒ claims Nos. 9, 10.

because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

   ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 9, 10.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the standard.

   ☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

   Novelty (N) Yes: Claims 4-8

	No:	Claims	1-3
Inventive step (IS)	Yes:	Claims	
	No:	Claims	4-8
Industrial applicability (IA)	Yes:	Claims	1-8
	No:	Claims	

2. Citations and explanations
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Re Item V Reasoned statement under Article 35.2 with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

It is referred in the following to the prior art as acknowledged by the applicant in figure 1 which is identified as D2. Reference is also made to the following documents:

D1: DE-A-19534663
D3: DE-A-4316643

V.1 The subject-matter of claim 1 is not new in view of D2.

D2 (see current application, figure 1) discloses an IVUS system which comprises a catheter (3) having mounted at or near its distal end an ultrasonic transducer array (implicit from D2); a catheter interface module (4); a display monitor (6); a control device (7) and a signal processing data entry and data storage device. Said IVUS systems are used with patients usually lying on a bed so that the additional feature of the bed is also implicitly present in the system according to D2. In D2, the catheter interface module, the display monitor and the control device are adapted to be located adjacent to the bed (The applicant may refer to the Guidelines, PCT/GL/3 Chapter III, § 4.8. It is further considered that the signal processing data entry and data storage device are also adapted to be located remotely from the bed at a sufficient distance to enable a clear space around the bed. Said features may be obtained with the system of D2 by adequately positioning the different elements (see also comments under section VIII).

The same objection could be raised on the basis of D1.

The subject-matter of claim 1 is thus not new.

V.2 The power distribution unit, the video recorder and the video printer disclosed in D2 are also adapted to be located remotely from the bed. In D2, the display monitor comprises a flat screen monitor.

The subject-matter of claims 2 and 3 is accordingly also not new.

V.3 The subject-matter of claim 4 differs from the system disclosed in D2 in that the control device incorporates means to enable control instructions to be given by voice and in that it incorporates voice recognition means for accepting and implementing those instructions.

The problem solved is to render control of the system easier.

A solution to that problem is known from a similar IVUS system disclosed in D3 (see D3, figures; column 3, lines 23-27) which also proposes to integrate a voice recognition system to an IVUS system. Since D3 directly relates to IVUS systems, It would also be obvious for the skilled man to consider its teaching and to incorporate said features in the device of D2.

The subject-matter of claim 4 is therefore not inventive.

V.4 It is also common practise when using catheters in order to accurately locate the catheter to provide additional imaging means. The use of a conventional IVUS system as illustrated in figure 1 with an additional ultrasound imaging system or an X-ray imaging system is accordingly considered to be obvious for the skilled man.

The subject-matter of claims 5 and 6 is accordingly not inventive in the sense of Article 33(3) PCT.

V.5 It is also suggested in D3 to provide Infra-Red transmitting means (see D3, column 2, lines 61-64). The mere integration of the display monitor to the catheter interface module does not appear to go beyond what may be expected from a skilled man in the course of normal practise.

The subject-matter of claims 7 and 8 accordingly does not meet the requirements of Article 33(3) PCT.

Re Item VIII Certain observations on the international application

VIII.1 The subject-matter of claim 1 is not clearly defined (Article 6 PCT).

The characterising features of claim 1 does not permit to identify the contribution of the invention over the prior art as for example illustrated in figure 1. It is in particular considered that said features merely relate to a particular use of a system known from the prior art. Such a use cannot justify the patentability of a known system, even if said use may fulfill the criteria of novelty or inventive step.

It is further noted in passing that in present case, a claim directed to such a use would also not be inventive since it would be obvious for the skilled man to locate the different elements of the system according to the intended purpose.

VIII.2 The same objection applies to claim 2.

VIII.3 Claim 1 is also not clear in that the terms "adjacent" and "remotely" have only a relative meaning.

Claims

1. An IVUS system which comprises:

a) a catheter (3) having mounted at or near its distal end an ultrasonic transducer array;

b) a catheter interface module (4) connected to the proximal end of the catheter (3);

c) a display monitor (12) ;

d) a control device (7, 13, 16);

e) a signal processing data entry and data storage device (9) for processing and storing the data derived from energisation of the ultrasonic transducer array to output a signal to the display monitor (12) in order to display an image of the interior of a patient's body;

f) a bed (14) for supporting a patient;

characterised in that:

(i) the catheter interface module(4), the display monitor (12) and the control device (7, 13, 16) are located adjacent to the bed (14) such as to be easily viewed and operated respectively by a clinician; and

(ii) the signal processing data entry and data storage device (9) is located remotely from the bed at a sufficient distance to enable a clear space around the bed for occupation by a medical team so that they can be adjacent to the patient.

2. An IVUS system as claimed in claim 1 characterised in that

there is located remotely from the bed one or more of the following:

(i) a power distribution unit (8);

(ii) a video recorder (10);

(iii) a video printer (11).

3. A system as claimed in claim 1 or 2 in which the display monitor comprises a flat screen monitor.

4. A system as claimed in any previous claim in which the control device incorporates means to enable control instructions to be given by voice and incorporates voice recognition means for accepting and implementing those instructions.

5. A system as claimed in any previous claim in combination with an ultrasound system which employs a transducer which in use is placed externally of the patient.

6. A system as claimed in any previous claim in combination with an X-ray system.

7. A system as claimed in any previous claim in which the control device includes an infra-red remote control device to enable control instructions to be given from a position adjacent the patient to the remotely located units.

8. A system as claimed in any previous claim in which the display monitor is mounted on the catheter interface module.

9. A method of arranging the component or units of the IVUS system as defined in any of claims 1 or claims 2 to 8 when dependant upon claim 1 which method comprises:

a) locating the catheter interface module (4) the image monitor (12) and the control device (7, 13, 16) adjacent the bed (14) such as to be easily viewed and operated respectively by a clinician; and

b) locating the signal processing data entry and data storage device (9) remotely from the bed (14) at a sufficient distance to enable a clear space around the bed for occupation by a medical team so that the team can be adjacent the patient.

10. A method as claimed in claim 9 comprising locating remote from the bed one or more of:

(i) a power distribution unit (8);

(ii) a video recorder (10);

(iii) a video printer (11).

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
IRL-P23-WO		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB99/04343	22/12/1999	06/01/1999
International Patent Classification (IPC) or national classification and IPC A61B8/12		
Applicant INTRAVASCULAR RESEARCH LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
04/08/2000	23.04.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Fontenay, P Telephone No. +49 89 2399 2646

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB99/04343

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-9	as originally filed			

Claims, No.:

1-10	as received on	22/12/2000	with letter of	20/12/2000

Drawings, sheets:

1/3-3/3	as originally filed

2. With regard to the **language,** all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   - ☐ the description, pages:
   - ☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)
see separate sheet

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 9, 10.

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 9, 10.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N) Yes: Claims 4-8

	No:	Claims	1-3
Inventive step (IS)	Yes:	Claims	
	No:	Claims	4-8
Industrial applicability (IA)	Yes:	Claims	1-8
	No:	Claims	

2. Citations and explanations
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Re Item V Reasoned statement under Article 35.2 with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

It is referred in the following to the prior art as acknowledged by the applicant in figure 1 which is identified as D2. Reference is also made to the following documents:

D1: DE-A-19534663
D3: DE-A-4316643

V.1 The subject-matter of claim 1 is not new in view of D2.

D2 (see current application, figure 1) discloses an IVUS system which comprises a catheter (3) having mounted at or near its distal end an ultrasonic transducer array (implicit from D2); a catheter interface module (4); a display monitor (6); a control device (7) and a signal processing data entry and data storage device. Said IVUS systems are used with patients usually lying on a bed so that the additional feature of the bed is also implicitly present in the system according to D2. In D2, the catheter interface module, the display monitor and the control device are adapted to be located adjacent to the bed (The applicant may refer to the Guidelines, PCT/GL/3 Chapter III, § 4.8. It is further considered that the signal processing data entry and data storage device are also adapted to be located remotely from the bed at a sufficient distance to enable a clear space around the bed. Said features may be obtained with the system of D2 by adequately positioning the different elements (see also comments under section VIII).

The same objection could be raised on the basis of D1.

The subject-matter of claim 1 is thus not new.

V.2 The power distribution unit, the video recorder and the video printer disclosed in D2 are also adapted to be located remotely from the bed. In D2, the display monitor comprises a flat screen monitor.

The subject-matter of claims 2 and 3 is accordingly also not new.

V.3 The subject-matter of claim 4 differs from the system disclosed in D2 in that the control device incorporates means to enable control instructions to be given by voice and in that it incorporates voice recognition means for accepting and implementing those instructions.

The problem solved is to render control of the system easier.

A solution to that problem is known from a similar IVUS system disclosed in D3 (see D3, figures; column 3, lines 23-27) which also proposes to integrate a voice recognition system to an IVUS system. Since D3 directly relates to IVUS systems, It would also be obvious for the skilled man to consider its teaching and to incorporate said features in the device of D2.

The subject-matter of claim 4 is therefore not inventive.

V.4 It is also common practise when using catheters in order to accurately locate the catheter to provide additional imaging means. The use of a conventional IVUS system as illustrated in figure 1 with an additional ultrasound imaging system or an X-ray imaging system is accordingly considered to be obvious for the skilled man.

The subject-matter of claims 5 and 6 is accordingly not inventive in the sense of Article 33(3) PCT.

V.5 It is also suggested in D3 to provide Infra-Red transmitting means (see D3, column 2, lines 61-64). The mere integration of the display monitor to the catheter interface module does not appear to go beyond what may be expected from a skilled man in the course of normal practise.

The subject-matter of claims 7 and 8 accordingly does not meet the requirements of Article 33(3) PCT.

Re Item VIII Certain observations on the international application

VIII.1 The subject-matter of claim 1 is not clearly defined (Article 6 PCT).

The characterising features of claim 1 does not permit to identify the contribution of the invention over the prior art as for example illustrated in figure 1. It is in particular considered that said features merely relate to a particular use of a system known from the prior art. Such a use cannot justify the patentability of a known system, even if said use may fulfill the criteria of novelty or inventive step.

It is further noted in passing that in present case, a claim directed to such a use would also not be inventive since it would be obvious for the skilled man to locate the different elements of the system according to the intended purpose.

VIII.2 The same objection applies to claim 2.

VIII.3 Claim 1 is also not clear in that the terms "adjacent" and "remotely" have only a relative meaning.

Claims

1. An IVUS system which comprises:

a) a catheter (3) having mounted at or near its distal end an ultrasonic transducer array;

b) a catheter interface module (4) connected to the proximal end of the catheter (3);

c) a display monitor (12) ;

d) a control device (7, 13, 16);

e) a signal processing data entry and data storage device (9) for processing and storing the data derived from energisation of the ultrasonic transducer array to output a signal to the display monitor (12) in order to display an image of the interior of a patient's body;

f) a bed (14) for supporting a patient;

characterised in that:

(i) the catheter interface module(4), the display monitor (12) and the control device (7, 13, 16) are located adjacent to the bed (14) such as to be easily viewed and operated respectively by a clinician; and

(ii) the signal processing data entry and data storage device (9) is located remotely from the bed at a sufficient distance to enable a clear space around the bed for occupation by a medical team so that they can be adjacent to the patient.

2. An IVUS system as claimed in claim 1 characterised in that

there is located remotely from the bed one or more of the following:

(i) a power distribution unit (8);

(ii) a video recorder (10);

(iii) a video printer (11).

3. A system as claimed in claim 1 or 2 in which the display monitor comprises a flat screen monitor.

4. A system as claimed in any previous claim in which the control device incorporates means to enable control instructions to be given by voice and incorporates voice recognition means for accepting and implementing those instructions.

5. A system as claimed in any previous claim in combination with an ultrasound system which employs a transducer which in use is placed externally of the patient.

6. A system as claimed in any previous claim in combination with an X-ray system.

7. A system as claimed in any previous claim in which the control device includes an infra-red remote control device to enable control instructions to be given from a position adjacent the patient to the remotely located units.

8. A system as claimed in any previous claim in which the display monitor is mounted on the catheter interface module.

9. A method of arranging the component or units of the IVUS system as defined in any of claims 1 or claims 2 to 8 when dependant upon claim 1 which method comprises:

a) locating the catheter interface module (4) the image monitor (12) and the control device (7, 13, 16) adjacent the bed (14) such as to be easily viewed and operated respectively by a clinician; and

b) locating the signal processing data entry and data storage device (9) remotely from the bed (14) at a sufficient distance to enable a clear space around the bed for occupation by a medical team so that the team can be adjacent the patient.

10. A method as claimed in claim 9 comprising locating remote from the bed one or more of:

(i) a power distribution unit (8);

(ii) a video recorder (10);

(iii) a video printer (11).

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference (if desired) (12 characters maximum) IRL-P23-WO

Box No. I TITLE OF INVENTION

ULTRASONIC VISUALISATION SYSTEMS

Box No. II APPLICANT

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country)

INTRAVASCULAR RESEARCH LIMITED
Unit 3a Centaurs Business Park
Grants Way
Isleworth
Middlesex TW7 5QD
GB

☐ This person is also inventor.

Telephone No.

Facsimile No.

Teleprinter No.

State (i.e. country) of nationality:

State (i.e. country) of residence:

This person is applicant for the purposes of: ☐ all designated states ☒ all designated States except the United States of America ☐ the United States of America only ☐ the States indicate in the Supplement Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: (Family name followed by given name; for a legal entity, full official Designation. The address must include postal code and name of country)

GLOVER, Richard Peter
23 Kerrison Road
Ealing
London W5 5NW
GB

This person is:

☐ applicant only

☒ applicant and inventor

☐ inventor only *(If this check-box is marked, do not fill in below.)*

State (i.e. country) of nationality: GB

State (i.e. country) of residence: GB

This person is applicant for the purposes of: ☐ all designated states ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicate in the Supplement Box

☐ Further applicants and/or (further) inventors are indicated on a continuation sheet.

BOX No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: ☒ agent ☐ common representative

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country)

ATKINSON BURRINGTON
The Technology Park
Shirland Lane
Sheffield S9 3PA

Telephone No. 0114 242 4581

Facsimile No. 0114 244 6050

Teleprinter No.

☐ Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Continuation of Box No. III **FURTHER APPLICANTS AND/OR (FURTHER) INVENTORS**

If none of the following sub-boxes is used, this sheet is not to be included with the request.

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country)

STENNING, Anthony David
13 Henchley Dene
Herrow Common
Guilford
Surrey GU4 7BH, GB

This person is:
- ☐ applicant only
- ☒ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below*

State (i.e. country) of nationality: **GB**

State (i.e. country) of nationality: **GB**

This person is applicant for the purposes of: ☐ all designated states ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicate in the Supplement Box

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country)

DICKINSON, Robert Julian
37 Broomwood Road
Battersea
London SW11 6HU, GB

This person is:
- ☐ applicant only
- ☒ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below*

State (i.e. country) of nationality: **GB**

State (i.e. country) of nationality: **GB**

This person is applicant for the purposes of: ☐ all designated states ☐ all designated States except the United States of America ☒ the United States of America only ☐ the States indicate in the Supplement Box

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country)

This person is:
- ☐ applicant only
- ☐ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below*

State (i.e. country) of nationality:

State (i.e. country) of nationality:

This person is applicant for the purposes of: ☐ all designated states ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicate in the Supplement Box

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country)

This person is:
- ☐ applicant only
- ☐ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below*

State (i.e. country) of nationality:

State (i.e. country) of nationality:

This person is applicant for the purposes of: ☐ all designated states ☐ all designated States except the United States of America ☐ the United States of America only ☐ the States indicate in the Supplement Box

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country)

This person is:
- ☐ applicant only
- ☐ applicant and inventor
- ☐ inventor only *(If this check-box is marked, do not fill in below*

☐ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No.V DESIGNATION OF STATES

The following designations are hereby made under Rule 4.9(a) *(mark the applicable check-boxes: at least one must be marked)*:

Regional Patent

- ☐ **AP** **ARIPO Patent:** **GH** Ghana, **GM** Gambia, **KE** Kenya, **LS** Lesotho, **MW** Malawi, **SD** Sudan, **SZ** Swaziland, **UG** Uganda, **ZW** Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT
- ☐ **EA** **Eurasian Patent:** **AM** Armenia, **AZ** Azerbaijan, **BY** Belarus, **KG** Kyrgyzstan, **KZ** Kazakhstan, **MD** Republic of Moldova, **RU** Russian Federation, **TJ** Tajikistan, **TM** Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT
- ☒ **EP** **European Patent:** **AT** Austria, **BE** Belgium, **CH and LI** Switzerland and Liechtenstein, **DE** Germany, **DK** Denmark, **ES** Spain, **FI** Finland, **FR** France, **GB** United Kingdom, **GR** Greece, **IE** Ireland, **IT** Italy, **LU** Luxembourg, **MC** Monaco, **NL** Netherlands, **PT** Portugal, **SE** Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT
- ☐ **OA** **OAPI Patent:** **BF** Burkina Faso, **BJ** Benin, **CF** Central African Republic, **CG** Congo, **CI** Côte d'Ivoire, **CM** Cameroon, **GA** Gabon, **GN** Guinea, **ML** Mali, **MR** Mauritania, **NE** Niger, **SN** Senegal, **TD** Chad, **TG** Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT *(if other kind of protection or treatment desired, specify on dotted line)* .....

National Patent *(if other kind of protection or treatment desired, specify on dotted line)*:

- ☐ **AL** Albania .....
- ☐ **AM** Armenia .....
- ☐ **AT** Austria .....
- ☐ **AU** Australia .....
- ☐ **AZ** Azerbaijan
- ☐ **BA** Bosnia and Herzegovina .....
- ☐ **BB** Barbados
- ☐ **BG** Bulgaria .....
- ☐ **BR** Brazil .....
- ☐ **BY** Belarus
- ☐ **CA** Canada
- ☐ **CH and LI** Switzerland and Liechtenstein
- ☐ **CN** China .....
- ☐ **CU** Cuba .....
- ☐ **CZ** Czech Republic .....
- ☐ **DE** Germany .....
- ☐ **DK** Denmark .....
- ☐ **EE** Estonia .....
- ☐ **ES** Spain .....
- ☐ **FI** Finland .....
- ☐ **GB** United Kingdom
- ☐ **GE** Georgia .....
- ☐ **GH** Ghana .....
- ☐ **GM** Gambia
- ☐ **GW** Guinea-Bissau .....
- ☐ **HU** Hungary .....
- ☐ **ID** Indonesia
- ☐ **IL** Israel .....
- ☐ **IS** Iceland
- ☒ **JP** Japan .....
- ☐ **KE** Kenya .....
- ☐ **KG** Kyrgyzstan .....
- ☐ **KP** Democratic People's Republic of Korea .....
- ☐ **KR** Republic of Korea .....
- ☐ **KZ** Kazakhstan .....
- ☐ **LC** Saint Lucia
- ☐ **LK** Sri Lanka
- ☐ **LR** Liberia
- ☐ **LS** Lesotho .....
- ☐ **LT** Lithuania
- ☐ **LU** Luxembourg
- ☐ **LV** Latvia
- ☐ **MD** Republic of Moldova .....
- ☐ **MG** Madagascar .....
- ☐ **MK** The former Yugoslav Republic of Macedonia .....
- ☐ **MN** Mongolia
- ☐ **MW** Malawi .....
- ☐ **MX** Mexico .....
- ☐ **NO** Norway
- ☐ **NZ** New Zealand .....
- ☐ **PL** Poland .....
- ☐ **PT** Portugal .....
- ☐ **RO** Romania
- ☐ **RU** Russian Federation .....
- ☐ **SD** Sudan
- ☐ **SE** Sweden
- ☐ **SG** Singapore
- ☐ **SI** Slovenia .....
- ☐ **SK** Slovakia .....
- ☐ **SL** Sierra Leone
- ☐ **TJ** Tajikistan .....
- ☐ **TM** Turkmenistan .....
- ☐ **TR** Turkey .....
- ☐ **TT** Trinidad and Tobago .....
- ☐ **UA** Ukraine .....
- ☐ **UG** Uganda .....
- ☒ **US** United States of America .....
- ☐ **UZ** Uzbekistan .....
- ☐ **VN** Viet Nam .....
- ☐ **YU** Yugoslavia .....
- ☐ **ZW** Zimbabwe .....

Check-boxes reserved for designating States (for the purposes of a national patent) which have become party to the PCT after issuance of this sheet:

- ☐ .....
- ☐ .....
- ☐ .....

In addition to the designations made above, the applicant also makes under Rule 4.9(b) all designations which would be permitted under the PCT except the designation(s) of _____.

The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. *(Confirmation of a designation consists of the filing of a notice specifying that designation and the payment of the designation and confirmation fees. Confirmation must reach the receiving Office within the 15-month time limit.)*

Box No. VI PRIORITY CLAIM Further priority claims are indicated in the Supplemental Box ☐

The priority of the following earlier application(s) is hereby claimed:

Country *(in which, or for which, the application was filed)*	Filing Date *(day/month/year)*	Application No.	Office of filing *(only for regional or international application)*
item (1) GB(UK)	06/01/99	9900133.1	
item (2)			
item (3)			

Mark the following check-box if the certified copy of the earlier application is to be issued by the Office which for the purposes of the present international application is the receiving Office (a fee may be required):

☐ The receiving Office is hereby requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s) : _____

Box No. VII INTERNATIONAL SEARCHING AUTHORITY

Choice of International Searching Authority (ISA) *(If two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):* ISA /_____

Earlier search *Fill in where a search (international, international-type or other) by the International Searching Authority has already been carried out or requested and the Authority is now requested to base the international search, to the extent possible, on the results of that earlier search. Identify such search or request either by reference to the relevant application (or the translation thereof) or by reference to the search request:*

Country (or regional Office): Date *(day/month/year)*: Number:

Box No. VIII CHECK LIST

This international application contains the following number of sheets:

1. request	: 4	sheets
2. description	: 10	sheets
3. claims	: 2	sheets
4. abstract	: 1	sheets
5. drawings	: 3	sheets
Total	: 20	sheets

This international application is accompanied by the item(s) marked below:

1. ☐ separate signed power of attorney
2. ☐ copy of general power of attorney
3. ☐ statement explaining lack of signature
4. ☐ priority document(s) *identified in Box No. VI as item(s):*
5. ☒ fee calculation sheet
6. ☐ separate indications concerning deposited microorganisms
7. ☐ nucleotide and/or amino acid sequence listing (diskette)
8. ☐ other *(specify)*:

Figure No. 2 of the drawings (if any) should accompany the abstract when it is published.

Box No. IX SIGNATURE OF APPLICANT OR AGENT

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).

A.G.H. BURRINGTON

For receiving Office use only

1. Date of actual receipt of the purported international application:
2. Drawings: ☐ received: ☐ not received:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:
4. Date of timely receipt of the required corrections under PCT Article 11(2):
5. International Searching Authority specified by the applicant: ISA /
6. ☐ Transmittal of search copy delayed until search fee is paid

For International Bureau use only

Date of receipt of the record copy by the International Bureau:

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 99/04343

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B8/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B G01S

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 43 16 643 A (SIEMENS AG) 16 December 1993 (1993-12-16) column 1, line 47 - line 49 column 2, line 35 - line 67	1,3
A	US 4 625 731 A (QUEDENS PHILLIP J ET AL) 2 December 1986 (1986-12-02) column 4, line 14 - line 37	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 March 2000	14 06. 2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Knüpling, M

INTERNATIONAL SEARCH REPORT

Inte tional application No.
PCT/GB 99/04343

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 8
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210.

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
See additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-3,6,7

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 8

The subject matter of claim 8 is defined by reference to the description and drawings which is not allowed by the PCT (see rule 6.2 PCT). The claim does not define any clear structural features or limitations. Consequently, the scope of the claim is not clear (see Article 6 PCT) and a meaningful search is not possible (Article 17 PCT).

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

1. Claims: 1-3,6,
7 (claim 7 if dependent on any of claims 1-3 or 6)

A remotely controllable intravascular ultrasound system

2. Claims: 4,5,
7 (claim 7 if dependent on any of claims 4 or 5)

Integration of an intravascular ultrasound system

INTERNATIONAL SEARCH REPORT

Int ation on patent family members

International Application No
PCT/ 99/04343

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE 4316643 A	16-12-1993	NONE	
US 4625731 A	02-12-1986	JP 61179139 A	11-08-1986

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
IRL-P23-WO		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/GB 99/04343	22/12/1999	06/01/1999
Applicant		
INTRAVASCULAR RESEARCH LIMITED et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 6 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readble form.

   ☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☒ **Certain claims were found unsearchable** (See Box I).

3. ☒ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

   ☒ the text is approved as submitted by the applicant.

   ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

   ☐ the text is approved as submitted by the applicant.

   ☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 2

   ☒ as suggested by the applicant.

   ☐ because the applicant failed to suggest a figure.

   ☐ because this figure better characterizes the invention.

   ☐ None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB 99/04343

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 8
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
See additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-3,6,7

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 8

The subject matter of claim 8 is defined by reference to the description and drawings which is not allowed by the PCT (see rule 6.2 PCT). The claim does not define any clear structural features or limitations. Consequently, the scope of the claim is not clear (see Article 6 PCT) and a meaningful search is not possible (Article 17 PCT).

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

1. Claims: 1-3,6,
7 (claim 7 if dependent on any of claims 1-3 or 6)

A remotely controllable intravascular ultrasound system

2. Claims: 4,5,
7 (claim 7 if dependent on any of claims 4 or 5)

Integration of an intravascular ultrasound system

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB 99/04343

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

In an IVUS system units are located outside or remote from the patient except for the display monitor (12), the catheter interface module (4) and the catheter (3) which are located adjacent the patient together with a control arrangement (13) to enable the said units to be remotely controlled from a position adjacent the patient.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/[redacted]99/04343

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B8/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B G01S

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 43 16 643 A (SIEMENS AG) 16 December 1993 (1993-12-16) column 1, line 47 - line 49 column 2, line 35 - line 67	1,3
A	US 4 625 731 A (QUEDENS PHILLIP J ET AL) 2 December 1986 (1986-12-02) column 4, line 14 - line 37	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 March 2000	14. 06. 2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Knüpling, M

1

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/GB 99/04343

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE 4316643 A	16-12-1993	NONE	
US 4625731 A	02-12-1986	JP 61179139 A	11-08-1986

PATENT COOPERATION TREATY

IRL-P23-WO

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING SUBMISSION OR TRANSMITTAL OF PRIORITY DOCUMENT

(PCT Administrative Instructions, Section 411)

To:

28 FEB 2000

ALAN BURRINGTON & ASSOCIATES
41 The Street
Ashtead
Surrey KT21 1AA
ROYAUME-UNI

Date of mailing (day/month/year) 15 February 2000 (15.02.00)	
Applicant's or agent's file reference	**IMPORTANT NOTIFICATION**
International application No. PCT/GB99/04343	International filing date (day/month/year) 22 December 1999 (22.12.99)
International publication date (day/month/year) Not yet published	Priority date (day/month/year) 06 January 1999 (06.01.99)
Applicant INTRAVASCULAR RESEARCH LIMITED et al	

1. The applicant is hereby notified of the date of receipt (except where the letters "NR" appear in the right-hand column) by the International Bureau of the priority document(s) relating to the earlier application(s) indicated below. Unless otherwise indicated by an asterisk appearing next to a date of receipt, or by the letters "NR", in the right-hand column, the priority document concerned was submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b).

2. This updates and replaces any previously issued notification concerning submission or transmittal of priority documents.

3. An **asterisk(*)** appearing next to a date of receipt, in the right-hand column, denotes a priority document submitted or transmitted to the International Bureau but not in compliance with Rule 17.1(a) or (b). In such a case, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

4. The **letters "NR"** appearing in the right-hand column denote a priority document which was not received by the International Bureau or which the applicant did not request the receiving Office to prepare and transmit to the International Bureau, as provided by Rule 17.1(a) or (b), respectively. In such a case, **the attention of the applicant is directed** to Rule 17.1(c) which provides that no designated Office may disregard the priority claim concerned before giving the applicant an opportunity, upon entry into the national phase, to furnish the priority document within a time limit which is reasonable under the circumstances.

Priority date	Priority application No.	Country or regional Office or PCT receiving Office	Date of receipt of priority document
06 Janu 1999 (06.01.99)	9900133.1	GB	09 Febr 2000 (09.02.00)

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer

Marc Salzman

Telephone No. (41-22) 338.83.38

Copy for the Elected Office (EO/US) PCT/GB99/04343

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and Administrative Instructions, Section 422)

To:

ATKINSON BURRINGTON
27-29 President Buildings
Firth Way
Sheffield S4 7UR
ROYAUME-UNI

Date of mailing (day/month/year)
26 September 2000 (26.09.00)

Applicant's or agent's file reference

IMPORTANT NOTIFICATION

International application No.
PCT/GB99/04343

International filing date (day/month/year)
22 December 1999 (22.12.99)

1. The following indications appeared on record concerning:

[ ] the applicant [ ] the inventor [X] the agent [ ] the common representative

Name and Address
ATKINSON BURRINGTON
The Technology Park
Skirland Lane
Sheffield S9 3PA
United Kingdom

State of Nationality

State of Residence

Telephone No.
01372 270900

Facsimile No.
01372 270899

Teleprinter No.

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

[ ] the person [ ] the name [X] the address [ ] the nationality [ ] the residence

Name and Address
ATKINSON BURRINGTON
27-29 President Buildings
Firth Way
Sheffield S4 7UR
United Kingdom

State of Nationality

State of Residence

Telephone No.
0114 275 2400

Facsimile No.
0114 275 6565

Teleprinter No.

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

[X] the receiving Office
[ ] the International Searching Authority
[X] the International Preliminary Examining Authority
[ ] the designated Offices concerned
[X] the elected Offices concerned
[ ] other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer
Aino Metcalfe

Telephone No.: (41-22) 338.83.38

Form PCT/IB/306 (March 1994)

003545318

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

To:
ATKINSON BURRINGTON
The Technology Park
Skirland Lane
Sheffield S9 3PA
ROYAUME-UNI

Date of mailing (day/month/year) 13 July 2000 (13.07.00)	
Applicant's or agent's file reference	**IMPORTANT NOTICE**

International application No.	**International filing date** (day/month/year)	**Priority date** (day/month/year)
PCT/GB99/04343	22 December 1999 (22.12.99)	06 January 1999 (06.01.99)

Applicant
INTRAVASCULAR RESEARCH LIMITED et al

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:
   JP,US

   In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:
   EP

   The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 49.1(a-bis)).

3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on
   13 July 2000 (13.07.00) under No. WO 00/40156

REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, **a demand for international preliminary examination** must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the **national phase**, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. (41-22) 740.14.35

Authorized officer
J. Zahra

Telephone No. (41-22) 338.83.38

Continuation of Form PCT/IB/308

NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION TO THE DESIGNATED OFFICES

Date of mailing (day/month/year)	IMPORTANT NOTICE
13 July 2000 (13.07.00)	
Applicant's or agent's file reference	**International application No.**
	PCT/GB99/04343

The applicant is hereby notified that, at the time of establishment of this Notice, the time limit under Rule 46.1 for making amendments under Article 19 has not yet expired and the International Bureau had received neither such amendments nor a declaration that the applicant does not wish to make amendments.

PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

BURRINGTON, Alan G.H.
ATKINSON BURRINGTON
The Technology Park
Skirland Lane
Sheffield S9 3PA
GRANDE BRETAGNE

PCT

WRITTEN OPINION

(PCT Rule 66)

Date of mailing *(day/month/year)*	21.09.2000
Applicant's or agent's file reference: IRL-P23-WO	**REPLY DUE** **within 3 month(s)** from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB99/04343	22/12/1999	06/01/1999

International Patent Classification (IPC) or both national classification and IPC

A61B8/12

Applicant

INTRAVASCULAR RESEARCH LIMITED et al.

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

I	☒	Basis of the opinion
II	☐	Priority
III	☒	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☐	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain document cited
VII	☐	Certain defects in the international application
VIII	☐	Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 06/05/2001.

Name and mailing address of the international preliminary examining authority:

European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized officer / Examiner

Fontenay, P

Formalities officer (incl. extension of time limits)
Edel, M
Telephone No. +49 89 2399 2426

I. Basis of the opinion

1. This opinion has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".*):

Description, pages:

1-9 as originally filed

Claims, No.:

1-8 as originally filed

Drawings, sheets:

1/3-3/3 as originally filed

2. The amendments have resulted in the cancellation of:

☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

3. This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application,

☒ claims Nos. 1-8,

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

Reference is made to the following document:

D1 = DE-A-19534663

The document D1 was not cited in the international search report. A copy of the document is appended hereto.

Re Item III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

III.1 The subject-matter of claim 1 is not clearly defined contrary to the requirements of Article 6 PCT.

Claim 1 is not clear as to its category. It is not clear from the present wording wether the claimed subject-matter refers to a system or to a method. Even, if dependent claims 2 and 3 suggest that claim 1 relates to a system, the features according to which the units making up the system are located outside or remote from the patient and that the display monitor, CIM and the catheter are located adjacent the patient refer to method steps as to the use of the IVUS system.

Moreover, references to the patient renders the claim even more unclear. It is in particular not clear from the proposed wording which are the structural limitations as to the structure or function of the claimed subject-matter which results from the location of different units of the IVUS system in relation to the patient.

A wording of the type "In an IVUS system... " should have been avoided since it throw doubts on the definition of the claimed subject-matter. It is in particular questioned, in the case that the claim should relate to a system, wether a complete system is defined or a part only of that system.

It is in particular not possible to identify the contribution of the present invention over a conventional IVUS system as may be for example illustrated in D1 (see D1, figure 2).

III.2 The reference to claim 12 in claim 6 should have been corrected and probably be replaced by a reference to claim 1 or 2.

III.3 The subject-matter of claim 8, which anyway has also not been searched, is not clearly defined because it is not directly derivable from the references to figures 2-5 which structural features define the invention. It is reminded that according to Rule 6.2(a) the claims shall not rely, in respect of the technical features of the invention, on references to the description or drawings.

III.4 It is accordingly not presently possible to carry out the examination of the present application.

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 1-3, 6, 7, 8 are so unclear that no meaningful opinion could be formed (*specify*):

see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 4, 5, 8.

PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

BURRINGTON, Alan G.H.
ATKINSON BURRINGTON
27-29 President Buildings
Firth Way
Sheffield S4 7UR
GRANDE BRETAGNE

PCT

WRITTEN OPINION

(PCT Rule 66)

Date of mailing *(day/month/year)*	15.01.2001
Applicant's or agent's file reference: IRL-P23-WO	**REPLY DUE** **within 2 month(s)** from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB99/04343	22/12/1999	06/01/1999

International Patent Classification (IPC) or both national classification and IPC

A61B8/12

Applicant

INTRAVASCULAR RESEARCH LIMITED et al.

1. This written opinion is the **second** drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

I	☒	Basis of the opinion
II	☐	Priority
III	☒	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☒	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain document cited
VII	☒	Certain defects in the international application
VIII	☒	Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 06/05/2001.

Name and mailing address of the international preliminary examining authority:
European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized officer / Examiner
Fontenay, P

Formalities officer (incl. extension of time limits)
Ullrich, C
Telephone No. +49 89 2399 2322

I. Basis of the opinion

1. This opinion has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".*):

Description, pages:

1-9 as originally filed

Claims, No.:

1-10 as received on 22/12/2000 with letter of 20/12/2000

Drawings, sheets:

1/3-3/3 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)
see separate sheet

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application,

☒ claims Nos. 9, 10,

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 9, 10.

2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrialapplicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1, 3, 5, 6
Inventive step (IS)	Claims	4, 7, 8

Industrial applicability (IA) Claims

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Re Item I: Basis for the opinion

I.1 The amended claims contain subject-matter extending beyond the content of the originally filed documents contrary to the requirements of article 34.2(b) PCT.

ARGUE The feature according to which the catheter interface module is connected to the proximal end of the catheter is not directly derivable from the application documents as filed. Figure 1 which relates to the prior art is not sufficient to support this feature.

ARGUE. see P1

ARGUE Feature "e" in current claim 1 also contains added subject-matter in that it relates to a data storage device identified by reference "9". However, according to the terminology employed in the application, reference 9 corresponds to the computer whereas a data storage device appears as reference "26". BUT

WHY? NON SEQUITUR

It has accordingly been assumed in the following that feature "b" merely referred to a catheter interface module without specifying any relation to the proximal end of the catheter. It has also been assumed that feature "e" read: a signal processing data entry and data storage (26) for processing and storing the data derived from energisation of the ultrasonic transducer array to output a signal to the display monitor (12) in order to display an image of the interior of a patient's body.

WHY WHERE IT STATES IT IS CONNECTED TO THE PROXIMAL END,

YES OK

WHAT IS THE PROBLEM?

I.2 The features of claim 2 are not directly derivable from the original application documents. The references to the power distribution unit, the video recorder or the video printer relate to figure 1 which describes the prior art. There is no statement to be found in the description specifying that said elements should form part of the claimed subject-matter

ARGUE

BUT AGAIN SEE P.2.

The following comments accordingly do not address claim 2.

Re Item V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

It is referred in the following to the prior art as acknowledged by the applicant in

figure 1 which is identified as D2. Reference is also made to the following documents:

D1: DE-A-19534663
D3: DE-A-4316643

V.1 The subject-matter of claim 1 is not new in view of D2.

D2 (see current application, figure 1) discloses an IVUS system which comprises a catheter (3) having mounted at or near its distal end an ultrasonic transducer array (implicit from D1); a catheter interface module (4); a display monitor (6); a control device (7) and a signal processing data entry and data storage device. Said IVUS systems are used with patients usually lying on a bed so that the additional feature of the bed is also implicitly present in the system according to D2. In D2, the catheter interface module, the display monitor and the control device may be located adjacent to the bed. It is further considered that the signal processing data entry and data storage device may be located remotely from the bed at a sufficient distance to enable a clear space around the bed. Said features may be obtained with the system of D2 by adequately positioning the different elements (see also comments under section VIII).

BUT D2 DOES NOT DISCLOSE THE CLAIMED ARRANGEMENT, ARGUE

The same objection could be raised on the basis of D1.

The subject-matter of claim 1 is thus not new.

V.2 In D2, the display monitor comprises a flat screen monitor. It is also common practise when using catheters in order to accurately locate the catheter to provide additional imaging means. The use of a conventional IVUS system as illustrated in figure 1 with an additional ultrasound imaging system or an X-ray imaging system is accordingly considered to be part of the prior art.

The subject-matter of claims 3, 5 and 6 is accordingly not new.

V.3 The subject-matter of claim 4 differs from the system disclosed in D2 in that the control device incorporates means to enable control instructions to be given by

voice and in that it incorporates voice recognition means for accepting and implementing those instructions.

The problem solved is to render control of the system easier.

A solution to that problem is known from a similar IVUS system disclosed in D3 (see D3, figures; column 3, lines 23-27) which also proposes to integrate a voice recognition system to an IVUS system. Since D3 directly relates to IVUS systems, It would also be obvious for the skilled man to consider its teaching and to incorporate said features in the device of D2.

The subject-matter of claim 4 is therefore not inventive.

It is also suggested in D3 to provide Infra-Red transmitting means (see D3, column 2, lines 61-64). The mere integration of the display monitor to the catheter interface module does not appear to go beyond what may be expected from a skilled man in the course of normal practise.

The subject-matter of claims 7 and 8 is accordingly also not inventive.

Re Item VII Certain defects in the international application

VII.1 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 is not mentioned in the description, nor is this document identified therein.

BUT D2 IS MENTIONED & THE EXAMINER RELIES ON D2

VII.2 Independent claim should be drafted in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate. ?

? it is already

VII.3 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT). This requirement also applies to the dependent claims. ?

they are

Re Item VIII Certain observations on the international application

VIII.1 The subject-matter of claim 1 is not clearly defined (Article 6 PCT).

The characterising features of claim 1 does not permit to identify the contribution of the invention over the prior art as for example illustrated in figure 1. It is in particular considered that said features merely relate to a particular use of a system as known from the prior art. Such a use cannot justify the patentability of a known system, even if said use may fulfill the criteria of novelty or inventive step.

THIS IS THE KEY ISSUE

It is further noted in passing that in present case, such a use would also not be inventive in that it would be obvious for the skilled man to locate the different elements of the system according to the intended purpose.

VIII.2 The same objection would have applied to claim 2.

Comments:

The applicant may file possible amendments by way of replacement pages in the manner stipulated by Rule 66.8(a) PCT. In particular, fair copies of the amendments should be filed preferably in triplicate.

Moreover, the applicant's attention is drawn to the fact that, as a consequence of Rule 66.8(a) PCT the examiner is not permitted to carry out any amendments under the PCT procedure, however minor these may be.

In order to facilitate the examination of the conformity of the amended application with the requirements of Article 34(2)(b) PCT, the applicant is requested to clearly identify the amendments carried out, no matter whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based (see also Rule 66.8(a) PCT).

Atkinson Burrington
Patent & Trademark Attorneys

Date : Wednesday 20 December 2000
By Fax : 00 49 89 2399 4465

Your Ref:
Our Ref : IRL-P23-WO

European Patent Office
Directorate General 2
Erhardtstrasse 27
D-80298 Munchen
Germany

Dear Sirs

INTERNATIONAL PATENT APPLICATION No PCT/GB99/04343
EARLIEST PRIORITY DATE: 06 JANUARY 1999
APPLICANT: INTRAVASCULAR RESEARCH LIMITED

With reference to the official letter of 21 September 2000 enclosing the Examiner's Written Opinion, the applicants hereby request that pages 10 to 12 be deleted and be replaced by the enclosed new pages 10 to 13.

The present claims have been cancelled and replaced by a new set of claims which have been drafted to firstly meet the Examiner's objection based on Article 6 PCT and secondly to clearly distinguish from the prior art referred to by the Examiner and also that contained in the International Search Report.

Independent claim 1 is directed to "An IVUS system" but it is submitted that it is clearly a combination of apparatus features. Claim 9 which refers to the components and units specified in claim 1 is a method claim. Claims 2 to 8 are essentially the same as the sub-claims previously in this application, the previous claim 8 having been deleted.

Although the Examiner has not expressed any opinion concerning the novelty, inventive step and industrial applicability of the present invention the applicants would submit the following comments to be taken into consideration by the Examiner when examining the enclosed new set of claims.

None of the citations is concerned with the problem addressed by the present invention which is to optimise the space around a patient so that the medical team has improved access to the patient whilst at the same time enabling the catheter images to be viewed by the clinician on a relatively small screen immediately adjacent the patient.

Continued overleaf...

27-29 President Buildings, President Way, Sheffield S4 7UR, England
Tel: +44 (0) 114 275 2400. Fax: +44 (0) 114 275 6565. email: post@atkinson-burrington.com
Registered Office of Atkinson Burrington Ltd. Registration Number 3808285. VAT Number GB 737 5725 06

Date : Wednesday 20 December 2000
By Fax : 00 49 89 2399 4465

Your Ref:
Our Ref : IRL-P23-WO

It is therefore submitted that the present claims define a novel and inventive combination of features over the disclosures in the citations, either taken singly or in combination.

It is also submitted that the present claims are directed to industrially applicable subject matter.

Yours faithfully

Alan Burrington
Atkinson Burrington

SR-12-016

Claims

1. An IVUS system which comprises:

a) a catheter (3) having mounted at or near its distal end an ultrasonic transducer array;

b) a catheter interface module (4) connected to the proximal end of the catheter (3);

c) a display monitor (12) ;

d) a control device (7, 13, 16);

e) a signal processing data entry and data storage device (9) for processing and storing the data derived from energisation of the ultrasonic transducer array to output a signal to the display monitor (12) in order to display an image of the interior of a patient's body;

f) a bed (14) for supporting a patient;

characterised in that:

(i) the catheter interface module(4), the display monitor (12) and the control device (7, 13, 16) are located adjacent to the bed (14) such as to be easily viewed and operated respectively by a clinician; and

(ii) the signal processing data entry and data storage device (9) is located remotely from the bed at a sufficient distance to enable a clear space around the bed for occupation by a medical team so that they can be adjacent to the patient.

2. An IVUS system as claimed in claim 1 characterised in that

there is located remotely from the bed one or more of the following:

(i) a power distribution unit (8);

(ii) a video recorder (10);

(iii) a video printer (11).

3. A system as claimed in claim 1 or 2 in which the display monitor comprises a flat screen monitor.

4. A system as claimed in any previous claim in which the control device incorporates means to enable control instructions to be given by voice and incorporates voice recognition means for accepting and implementing those instructions.

5. A system as claimed in any previous claim in combination with an ultrasound system which employs a transducer which in use is placed externally of the patient.

6. A system as claimed in any previous claim in combination with an X-ray system.

7. A system as claimed in any previous claim in which the control device includes an infra-red remote control device to enable control instructions to be given from a position adjacent the patient to the remotely located units.

8. A system as claimed in any previous claim in which the display monitor is mounted on the catheter interface module.

9. A method of arranging the component or units of the IVUS system as defined in any of claims 1 or claims 2 to 8 when dependant upon claim 1 which method comprises:

a) locating the catheter interface module (4) the image monitor (12) and the control device (7, 13, 16) adjacent the bed (14) such as to be easily viewed and operated respectively by a clinician; and

b) locating the signal processing data entry and data storage device (9) remotely from the bed (14) at a sufficient distance to enable a clear space around the bed for occupation by a medical team so that the team can be adjacent the patient.

10. A method as claimed in claim 9 comprising locating remote from the bed one or more of:

(i) a power distribution unit (8);

(ii) a video recorder (10);

(iii) a video printer (11).

Abstract of the Disclosure

In an IVUS system units are located outside or remote from the patient except for the display monitor, the catheter interface module and the catheter which are located adjacent the patient together with a control arrangement to enable the said units to be remotely controlled from a position adjacent the patient.

Atkinson Burrington
Patent & Trademark Attorneys

Date : Thursday, 15 March 2001
By Fax : 00 49 89 2399 4465

Your Ref:
Our Ref : 2060-P123-WO

European Patent Office
Directorate General 2
Erhardtstrasse 27
D-80298 Munchen
Germany

Dear Sirs

INTERNATIONAL PATENT APPLICATION No PCT/GB99/04343
EARLIEST PRIORITY DATE: 06 JANUARY 1999
APPLICANT: INTRAVASCULAR RESEARCH LIMITED

We would refer to the Official Letter of 15 January 2001 enclosing a second Written Opinion.

The objections now made by the Examiner in connection with the amended set of claims which were filed in response to the first Written Opinion have now been carefully considered, the applicants comments on them being as follows.

The claims filed in response to the first Written Opinion are in two part form and do include reference numerals. The Examiner's objections at VII.2 and VII.3 are therefore not understood.

With regard to the Examiner's comment at VII.1 it is submitted that as D2 is referred to in the introduction and furthermore as the Examiner apparently regards D2 as being at least as relevant as D1 it is not necessary to also refer to D1 in the introduction.

With regard to the Examiner's objections concerning alleged added subject matter it is submitted that the introduction on page 1 makes it quite clear that the present invention relates to a system which has all the elements specified in that introduction. The applicants therefore disagree with the Examiner's statement that "Figure 1 which relates to the prior art is not sufficient to support this feature".

With regard to feature "e" and the reference numerals "9" and "26" unless the Examiner is merely saying that the reference "9" should in fact be the reference "26" the substance of the Examiner's objection is not understood.

Continued overleaf:...

Date : Thursday, 15 March 2001
By Fax : 00 49 89 2399 4465

Your Ref:
Our Ref : 2060-P123-WO

In any event the computer 9 of the IVUS system would in fact be involved in the signal processing, data entry and data storage. Furthermore the reference "26" is stated at line 12 on page 7 relates to the output on the ADC 24 of raw digital data.

With regard to the Examiner's objection at paragraph 1.2 concerning claim 2 the applicant submits that there is a basis for this claim in the introduction to the specification on pages 1 and 2 for the reason indicated earlier in this letter, namely that the introduction makes it quite clear that the present invention relates to a system having all the elements set out in that introduction.

In paragraph V.1 the Examiner expresses the view that the subject matter in claim 1 is not novel in view of the disclosure in D2, the prior art specification referred to by the applicant in the present introduction.

The fact that the Examiner states "It is further considered that the signal processing data entry and data storage device may be located remotely from the bed at a sufficient distance to enable a clear space around the bed." would appear to indicate that the Examiner's real objection is one of obviousness and not of lack of novelty. In any event the applicant would submit that none of the prior art discloses the inventive concept which is stated in the characterising part of claim 1 and emphasised at lines 11 to 13 on page 4 of the present specification.

On the question of "obviousness" the applicants would make the following points.

As indicated in the introduction the prior art arrangement of the various elements making up the IVUS system involves the use of a so-called "cart" which carries the various elements referred to in the introduction on page 1 including a display screen. The tendency has thus been to locate all the relevant elements of the IVUS system within the catheter laboratory and as close to the patient as is consistent with leaving sufficient room for the medical team to work around the patient. This approach has the disadvantages outlined in the introduction of the present specification.

The applicant has appreciated that by relocating certain elements of the IVUS system remote from the patient, and typically within an existing room outside the operating area itself, the disadvantages referred to can be overcome.

This approach goes against the accepted tendency to try to locate all the elements of the IVUS system as close as possible to the patient. It is therefore submitted that because the applicant's approach goes against the accepted current trend that it is not obvious.

In paragraph VIII. the Examiner objects to claim 1 on the basis that "the subject matter.....is not clearly defined"". The Examiner further goes on to state that in any event even if the criteria of novelty and inventive step are satisfied by claim 1 this claim cannot be allowed.

Continued overleaf:...

Date : Thursday, 15 March 2001
By Fax : 00 49 89 2399 4465

Your Ref:
Our Ref : 2060-P123-WO

The applicant's understanding of this objection by the Examiner is that he attaches no importance to the limitations in claim 1 as to the relative locations of the various elements making up the known IVUS system and as a consequence interprets claim 1 as simply covering the combination of those elements however physically arranged and located in relation to one another.

The Examiner further adds that in any event "such a use" It is submitted that the Examiner's interpretation of claim 1 as a "use" claim is mistaken because it quite specifically sets out the novel and inventive characteristic of the physical positional interrelationship of the various elements of the IVUS system.

For the reasons already given earlier in this letter such a physical arrangement is both novel and unobvious over the prior art.

It would appear to the applicant that the Examiner in paragraph VIII.1 is making a very basic objection to the effect that in his view it is not possible to obtain a patent for a novel physical positional arrangement of a known set of integers, in this case the elements making up a known IVUS system. As a general proposition the applicant would submit that it cannot be valid because many patents relate to the physical relationship between a group of known elements, the invention lying in that relationship and not in the combination of known elements itself. It would appear to the applicant that the Examiner seems to take the view that this general proposition cannot apply to the present invention.

Yours sincerely

Alan Burrington
Atkinson Burrington

Enc

LW-03-288